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Delegate Holy Seibold
Chair, Technology and Innovation Subcommittee
Virginia House of Delegates
General Assembly Building
201 North 9th Street
Richmond, VA 23219

Chair Seibold,

On behalf of AdvaMed, the MedTech Association, I am writing to register our continued interest in, and potential concern with, HB 747. Artificial Intelligence (AI) advancements in the medtech industry play a major role in improving patients' lives through innovative care, reduced healthcare costs, and improved patient outcomes. Unlike many other industries, the use of AI in medical technology is already subject to strict regulation by the FDA, which includes among its submission criteria the assessment of the mitigation of unwanted bias. Additional state regulations could negatively impact the use of AI for patient care and would likely provide no additional protections for patients. We are continuing to review this legislation and look forward to continued discussions with the author.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 500 members range from emerging companies to large multinationals, and include traditional device, diagnostic, medical imaging, and digital health technology companies.

The emergence of AI and machine learning (ML) is transforming every sector, from retail and finance to transportation. Despite its recent emergence in public consciousness, AI is not a new concept to the Food and Drug Administration (FDA) or the medical technology (medtech) industry. Over the last 25 years, the FDA has reviewed and authorized more than 700 AI/ML medical devices – a number that continues to grow.

Today, more than 80% of in-market medical technology products utilizing AI/ML perform diagnostic functions to assist clinicians in decision-making. Predominantly, these devices are not making independent decisions on diagnoses or treatment pathways; rather they provide the clinician with better data and imaging results. Further, the FDA reviews include analysis of adequate mitigation of unwanted bias and performance of the device and algorithm.

Additionally, most AI/ML-enabled medical devices are cleared or approved with "locked" algorithms. While these devices collect data that will improve the algorithm for a new FDA review, the devices are not reacting to data and generating independent or changing outputs. Notably, any algorithm modifications must be approved by the FDA and the FDA's post-market monitoring tools. Just as adverse event reporting and proscribed surveillance of medical devices, these requirements provide additional transparency.

AdvaMed appreciates the opportunity to comment on this legislation and looks forward to the continued dialogue and refinement on this legislation.

Sincerely,

Bobby Patrick, VI
Vice President, State Government, Regional Affairs, and Alliance Development
AdvaMed